

Remarks

The above amendments and these remarks are submitted in response to the Office Action of January 20, 2000, in which the Examiner rejected claims 1-18. In particular, claims 1-9 stand rejected under 35 U.S.C. §112 ¶2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-4, 6, 8, 10-13, and 15-18 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5, 281, 199 to Ensminger et al. ("Ensminger patent"). Claims 1-18 stand rejected under 35 U.S.C. §103(a) as unpatentable over Ensminger in view of U.S. Patent No. 5, 607, 390 to Patsalos et al. ("Patsalos patent").

**I. §112 Rejection**

Claims 1-9 were rejected under 35 U.S.C. §112 ¶2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that claim 1 recites a method step, but no method steps were included. Claim 1 has been amended to recite the steps of providing a fluid for analysis, providing an access means for accessing the fluid, accessing the fluid, and analyzing the fluid. Since claim 1 now includes method steps, and claims 2-9 depend on and incorporate all of the limitations of claim 1, the Examiner's basis for this rejection should be obviated.

**II §102 Rejection**

Claims 1-4, 6, 8, 10-13, and 15-18 were rejected under 35 U.S.C. §102(b) as being anticipated by Ensminger. The Examiner is respectfully reminded that in order for a reference to anticipate an invention, each element of the invention must be disclosed in the reference. Independent

claims 1, 10, and 16, as amended, and the claims dependent thereon, are not anticipated by the Ensminger patent for at least the reasons explained below.

Independent claims 1, 10 and 16 have been amended to include the element of a self sealing diaphragm in the access means. The self sealing diaphragm allows for multiple punctures with a needle or other sharp accessing instrument in order to access bodily fluids, or to introduce fluids into the body. The self sealing diaphragm finds support in the specification on page 8, lines 10-11.

In contrast, the Ensminger patent discloses a valve system using a multi-element leaflet valve assembly. *Page 9, Lines 60-61.* Every embodiment of the Ensminger device uses a multi element valve system. A valve system comprising a unitary diaphragm, such as that of the present invention, is not disclosed or taught in the patent.

The claims are not anticipated by Ensminger, because the element of a self sealing diaphragm is not disclosed in the reference. Ensminger discloses a valve system that is 1) a multi element system, and 2) a leaflet valve assembly. The present invention has neither of these. Claims 1, 10, and 16, as amended, call for a self sealing diaphragm. The self sealing diaphragm comprises a diaphragm element that allows a sharp instrument to puncture it, and then seals itself as the instrument is retracted. The leaflet valve assembly in the Ensminger patent comprises two disks having slits defining two or more deflectable valve leaves. In use, a filament running through the passageway engages the leaflet valve assembly causing the valve elements to deflect.

The device of the Ensminger patent and the present invention function in two very different ways. Ensminger does not disclose or teach a self sealing diaphragm. It is respectfully submitted that the Ensminger device could not employ such an element, since a feature of the Ensminger device is an

angled pathway, or needle stop, which prevents sharp, rigid objects, such as needles, from penetrating the valve system.

For at least the preceding reasons, claims 1, 10, and 16, as amended, are not anticipated by Ensminger.

Because claims 2-4, 6, and 8 depend on and incorporate all of the limitations of claim 1, the above arguments apply a fortiori to this ground for rejection. Because claims 11-13, and 15 depend on and incorporate all of the limitations of claim 10, the above arguments apply a fortiori to this ground for rejection. Because claims 17 and 18 are dependent on and incorporate all of the limitations of independent claim 16, the above arguments apply a fortiori to this ground for rejection. Thus, claims 2-4, 6, 8, 11-13, 15, and 17-18 are not anticipated by the Ensminger patent.

### III §103 Rejection

The Examiner rejected claims 1-18 as being obvious under §103(a) over Ensminger in view of Patsalos. It is respectfully submitted that the claims are not obvious over Ensminger in view of Patsalos because the asserted combination is not proper for at least three reasons: first, there is no suggestion in either patent that they be combined as asserted by the Examiner, second, Ensminger teaches away from the present invention, and third, it would be functionally impossible to modify the Ensminger device, whether in view of Patsalos or not, to achieve the present invention as claimed in the amended claims. Even if the asserted combination were proper, it would fail to teach applicant's invention because it would not disclose or teach a device or method for detecting the concentration and/or existence of substances in body fluids as claimed in the amended claims, i.e., using a self sealing diaphragm. Finally,

applicant notes that the asserted combination would not teach or disclose applicant's anchoring system, and has added claims to that feature.

As discussed above, the Ensminger patent discloses and teaches only a multi element leaflet valve assembly for use in the valve chamber, whereas amended claims 1, 10, and 16 recite a self sealing diaphragm. Thus, the Ensminger invention teaches away from the present invention.

Further, the Ensminger patent discloses a "needle stop" feature in the passageway. *Page 9, Lines 65-67.* This feature is a bend in the shaft which prevents a needle or any other sharp rigid accessing instrument from entering the valve assembly of the invention so as to not puncture the valve assembly. *Page 8, Lines 9-12.* In contrast, the self sealing diaphragm in the present invention is meant to be punctured by sharp accessing instruments. Clearly, one skilled in the art would not look to the Ensminger patent for a disclosure or teaching about self sealing diaphragms.

The Patsalos patent discloses a dialysis probe for insertion into a body, including a tubular dialysis membrane closed at its distal end, an inlet tube for supplying perfusion liquid into the body of the dialysis membrane, an outlet tube for the exit of perfusion fluid from the body of the dialysis membrane, and an anchoring system in which a generally rectangular shaped anchor is sutured to the skin, and the dialysis probe is connected to the anchor by adhesion. The Examiner suggested that it would have been obvious to one of ordinary skill in the art to use Patsalos et al's microdialysis probe in combination with Ensminger et al's access device for analyzing body fluids, but even if so, the combination would fail to disclose or teach applicant's invention as claimed in the amended claims, namely, it would not disclose or teach a device for detecting the concentration and/or existence of substances in body fluids comprising an access means with a self sealing diaphragm for accessing the

interior of the body, wherein the access means is implantable in the body and adapted to allow access to the body fluids through said self sealing diaphragm as recited in amended claims 1, 10 and 16. Rather, it would teach Ensminger modified by Patsalos, i.e., an implantable access device having a pathway with a needle stop, employing a multi unit leaflet valve assembly, in which a microdialysis probe may be used.

Added dependent claims 19-24 are directed to the anchor of the present invention. The present invention includes a generally disc shaped anchoring system for attaching and/or stabilizing the port body in or under the skin. The disk shaped anchor of the present invention functions by being wider than the port body, thus preventing the port body from being detached. The sides of the port body have a longitudinal axis, which is generally perpendicular to the disc shaped anchor. The sides of the port body are in contact with the skin, and prevent traversal movement of the port. In contrast, the Ensminger patent discloses an anchoring system that is a base section sutured or stapled to supporting tissue. The Ensminger device is quite bulky and heavy compared to the present invention, and thus requires more support (in the form of sutures or staples) to stabilize and anchor it. Thus, it would not have been obvious to one of ordinary skill in the art to modify the Ensminger device to achieve or provide the present invention as claimed in the added claims directed to the applicant's anchor. An advantage of the anchoring system of the present invention is that it does not require sutures or staples, and thus eliminates the risk of infection resulting from the use of them.

For at least the preceding reasons, it is submitted that the present invention is not obvious over Ensminger in view of Patsalos.

**IV Drawings**

The Examiner objected to the drawings under 37 CFR 1.83(a), which requires that the drawings show every feature of the invention specified in the claims. The drawings are missing the test sensor of claims 4 and 12, and the microdialysis probe of claims 9 an 14. The test sensor, which has support on page 9, lines 11, 13, and 16 of the specification, has been added to the drawing as elements 28 and 29. The specification has been amended to reflect the assignment of elements 28 and 29 to the drawing. The microdialysis probe, which has support on page 6, lines 5-6 has also been added to the drawings. Figure 2 has been added to show the microdialysis probe. The specification has been amended to reflect the use of a microdialysis probe in the detailed description, along with its assigned element in the drawings and the introduction of Figure 2. These actions are supported by the original disclosure, and should obviate the Examiner's objections regarding the drawings.

The Examiner also objected to the drawings as failing to comply with 37 CFR 1.84(p)(5) because reference 20 was included in the drawing, but not mentioned in the specification. Reference 20 has been deleted and will be so in the formal drawings when submitted.

Upon receiving the Notice of Allowance, the applicant will submit formal drawings embodying the noted changes.

**V New Claims**

New claims 19-24 have been added. The new claims are directed to the anchoring system of the present invention, and find support in the specification on page 8 at approximately lines 7-9. "The port body 10 comprises a shaft section 11 to which an approximately disc-shaped anchoring section 13 is attached, acting as an anchor or attachment for anchoring, attaching and/or stabilizing the port body

10 in (or under) the skin." *Specification, Page 8.* Further searching should not be required by the Examiner.

**VI      Fees**

The above amendments add four dependent claims in excess of those previously paid for, generating additional fees in the amount of \$72.00 (four claims in excess of twenty), and a petition for a two month extension of time to respond is being submitted herewith. Thus, additional fees of \$72.00 and \$380.00, respectively, for a total of \$452.00, are due. The Office is authorized in the petition and hereby to charge Deposit Account 04-1420 \$452.00 to cover these fees. It is believed that no other fees should be due in connection with this communication or the petition; however, the Office is also hereby authorized to charge any deficiency, or credit any overpayment to Deposit Account 04-1420.

**VII    Conclusion**

In view of the above amendments and preceding remarks, it is urged respectfully that the rejection of the claims be reconsidered, and that the claims be allowed. However, if the Examiner believes that any issues remain unresolved, he is invited to telephone the undersigned to expedite allowance.

Respectfully submitted,

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